

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

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Office
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Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing: 18 March 1999 (18.03.99)	
International application No.: PCT/AU98/00723	Applicant's or agent's file reference: 2093636/JMS
International filing date: 04 September 1998 (04.09.98)	Priority date: 05 September 1997 (05.09.97)
Applicant: DOYLE, Ian, Ross et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International preliminary Examining Authority on:
05 January 1999 (05.01.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer:</p> <p>J. Zahra</p> <p>Telephone No.: (41-22) 338.83.38</p>
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19

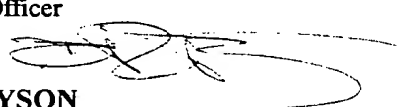
PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 13 JUL 1999

WIPO PCT

Applicant's or agent's file reference 2093636/JMS/TDO/LMa	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU 98/00723	International filing date (day/month/year) 4 September 1998	Priority Date (day/month/year) 5 September 1997
International Patent Classification (IPC) or national classification and IPC Int. Cl.⁶ G01N 33/68		
Applicant THE FLINDERS UNIVERSITY OF SOUTH AUSTRALIA et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 5 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input checked="" type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 5 February 1999	Date of completion of the report 7 July 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer  ISOBEL TYSON Telephone No. (02) 6283 2563

I. Basis of the report1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , filed with the letter of .
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , filed with the letter of .
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , filed with the letter of .
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , filed with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 6,11,13-36	YES
	Claims 1-5, 7-10,12	NO
Inventive step (IS)	Claims 6,11,13-35	YES
	Claims 1-5, 7-10,12,36	NO
Industrial applicability (IA)	Claims 1-36	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)**NOVELTY(N) and INVENTIVE STEP(IS): Claims 1-5, 7-10, 12, 36****JP 4009665 A**

This document discloses a method of determining a lung disease marker protein in blood using SP-A antibodies. This document therefore anticipates the present invention of claims 1,5, and 7 which are thus considered not novel or inventive.

Japanese J. Thor. Dis., 33(I), Nov. 1995, pp 1219-25

This document discloses a correlation between SP-A levels and lung disease, in particular a rise in SP-A levels in sera. The present invention as claimed in claims 1-5, 7- 10 and 12 are therefore not novel or inventive.

Japanese J. Thor. Dis., 34 Supp., Dec. 1996, pp 181-85

This document discloses that measurement of SP-A and SP-D in sera can provide an easily identifiable and useful clinical marker for diagnosing lung disease.

Thus, claims 1-5,7-10 and 12 are not considered novel or inventive in light of this document.

Derwent Accession Number 94-00758/01

This document discloses the detection and assay of SP-D in sera, which is useful for improved diagnosis of lung disease. Thus, claims 1-5 are not novel or inventive in light of this document.

EP 511011, A1

This document discloses detecting and measuring SP-A in blood and correlating SP-A levels, or a lack thereof, to a risk of Respiratory Distress Syndrome.

Thus, claims 1-5 and 7 are not novel or inventive in light of this document.

Am. J. Resp. & Crit. Care Med., 152(6 Pt. 1), Dec 1995, pp 1860-66

This document discloses a correlation between SP-D and lung disease, having first determined SP-D levels in sera and BAL fluids. This measurement of SP-D in sera is used as an easily identifiable and useful clinical marker for diagnosing lung diseases.

Thus, Claims 1-5, 7- 10 and 12 are not novel or inventive in light of this document.

VI. Certain documents cited**1. Certain published documents (Rule 70.10)**Application No.
Patent No.Publication date
(day/month/year)Filing date
(day/month/year)Priority date (valid claim)
(day/month/year)

US 5670328

23 September 1997

7 March 1995

7 March 1995

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure referring to
non-written disclosure
(day/month/year)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : Box V

Respiration, 62(2), 1995, pp 64-69

This document discloses determination of SP-A concentration in sera of patients with various lung diseases. This has led to SP-A being used as a marker for diagnosing lung diseases.

Thus, claims 1-5, 7-10 and 12 are not novel or inventive.

INVENTIVE STEP (IS): Claim 36

Claim 36 cannot be considered inventive, being as it is to a mere spatial arrangement of known integers with no working interrelationship.

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G01N 33/68	A1	(11) International Publication Number: WO 99/13337 (43) International Publication Date: 18 March 1999 (18.03.99)
(21) International Application Number: PCT/AU98/00723 (22) International Filing Date: 4 September 1998 (04.09.98) (30) Priority Data: PO 8999 5 September 1997 (05.09.97) AU PP 5062 4 August 1998 (04.08.98) AU (71) Applicant (for all designated States except US): THE FLINDERS UNIVERSITY OF SOUTH AUSTRALIA [AU/AU]; Sturt Road, Bedford Park, S.A. 5042 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): DOYLE, Ian, Ross [AU/AU]; 11 Trumara Road, Marino, S.A. 5049 (AU). BERSTEN, Andrew, David [AU/AU]; 33 Marine Parade, Seacliff, S.A. 5049 (AU). NICHOLAS, Terence, Evan [AU/AU]; 31 Malcolm Street, Bedford Park, S.A. 5042 (AU). (74) Agents: SLATTERY, John, M. et al.; Davies Collison Cave, 1 Little Collins Street, Melbourne, VIC 3000 (AU).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: A METHOD OF DIAGNOSIS		
(57) Abstract <p>The present invention relates generally to a method of diagnosing or predicting the development of lung damage and more particularly, to a method of diagnosing or predicting the development of alveolo-capillary membrane damage. The method of the present invention is useful <i>inter alia</i> for detecting lung damage or predicting the development of lung damage such as that caused by noxious agents or as an undesirable side effect resulting from exposure to a therapeutic agent and for monitoring the progress of lung damage.</p>		

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EE	Estonia						

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 98/00723

A. CLASSIFICATION OF SUBJECT MATTER					
Int Cl ⁶ : G01N 33/68					
According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELDS SEARCHED					
Minimum documentation searched (classification system followed by classification symbols) IPC C12Q G01N					
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC as above					
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) MEDLINE pulmonary, surfactant, SP-A, SP-B, SP-C, SP-D WPAT lung, disease, blood.					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
P, X	US 5670328 (INOUE, T. et al), 23 September 1997 - see whole document	1			
X	JP 04009665 (TEIJIN), 14 January 1992 - see abstract	1, 5			
X	Japanese Journal of Thoracic Diseases, 33 (11), November 1995, pp. 1219-25, ABE, S. et al. - see abstract	1-5, 7-10, 12			
<div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex </div>					
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> <p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 33%; vertical-align: top;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </td> <td style="width: 33%;"></td> </tr> </table>			<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>	
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>				
Date of the actual completion of the international search 19 November 1998		Date of mailing of the international search report - 3 DEC 1998			
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer ISOBEL TYSON Telephone No.: (02) 6283 2563			

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 98/00723

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Japanese Journal of Thoracic Diseases, (December 1996), 34 Suppl. 181-5, HONDA, Y. - see abstract	1-5, 7-10, 12
X	Derwent Accession No. 94-007558/01, Class S03, WO 9325701-A1 (YAMASA CORPORATION), 23 December 1993	1-5
X	EP 511011 (SURFACE ACTIVE LIMITED), 28 October 1992 - see whole document	1-5
X	American Journal of Respiratory and Critical Care Medicine, (December 1995), 152 (6 Pt 1), pp 1860-6, HONDA, Y. et al - see abstract	1-5, 7-10, 12
X	Respiration, (1995), 62(2), pp 64-9, HONDA, Y. et al - see abstract	1-5, 7-10, 12
P, X	American Journal of Respiratory and Critical Care Medicine, (October 1997), 156 (4 Pt 1), pp 1217-29, DOYLE, I.R., et al - see abstract	1, 5, 6, 7, 13, 14, 18
P, X	Pediatrics, (December 1997), 100(6), pp 998-1003, CLEARY, G.M., et al - see abstract	1, 5, 6.
P, X	European Respiratory Journal, (April 1998), 11(4), pp 801-3, HERMANS, C. et al - see abstract	1, 5, 6

International application No.
PCT/AU 98/00723

Information on patent family members

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	5 670 328	AU	43550/93	EP	602248	WO	9325701
EP	511011	AP	257	AU	16618/92	CN	1069124
		EP	582595	HU	66753	IL	101690
		NZ	242510	US	5573920	WO	9219973
		ZA	9202978				
<p style="text-align: right;">END OF ANNEX</p>							